

REMARKS

Introduction

Claims 9, 17-19, 24 and 25 are currently pending. Claims 9, 17, 19, 24 and 25 have been amended. Support for these amendments may be found throughout the specification, for example, in Figure 4 and the claims as filed.

The remaining claims have been withdrawn. Applicant expressly reserves the right to request rejoinder of these claims or to file divisional application(s) directed to these claims.

Rejection under 35 U.S.C. § 101

The Examiner has rejected claims 9, 17-19, 24 and 25 under 35 U.S.C. § 101 because the claims allegedly lack a specific or substantial credible utility. Applicants disagree for at least the reasons below.

The specification teaches that the TB2 gene is differentially expressed in samples from patient's suffering from AD when compared to healthy subjects. For example, the specification shows in Table 1 and the description of Table 1 that subtractive suppressive microarray hybridization comparing healthy control persons with AD patients revealed that the TB2 gene was differentially expressed in the two groups. This differential expression is further shown using quantitative RT-PCR. *See* figures 2 and 3 and description thereof.

This description, along with the specification as a whole, establishes a relationship between the expression of the TB2 gene and neurodegenerative diseases, such as AD. This relationship coupled with the identity of the TB2 protein (see SEQ ID NO. 1) has substantial and credible utility as a marker for detecting neurodegenerative diseases. This utility as a marker is shown in the specification in figures 2 and 3 and tables 1 and 2 where the level of TB2 was determined in AD patients as compared to healthy controls. The use of TB2 as a screening target is also disclosed in the specification at page 17 (bottom) through page 20. Thus, the pending claims directed to ligand binding assays utilizing TB2 as a marker and/or screening target have a substantial and credible

utility in detecting and treating neurodegenerative diseases like AD, as indicated in the specification.

As claims 17-19, 24 and 25 depend either directly or indirectly from claim 9, they also have a specific and credible utility by virtue of their dependency on claim 9. Therefore, for at least the above reasons, Applicant believes the rejection under 35 U.S.C. § 101 is improper and its withdrawal is hereby requested.

Rejections under 35 U.S.C. § 112

This section will discuss each of the 112 rejections in the Office Action in turn. The Examiner has rejected the claims under 112 as allegedly lacking utility. The above arguments regarding utility apply equally here as well.

The Examiner has rejected claims 9 and 17 under 112 second paragraph as allegedly being indefinite. Solely to expedite prosecution, claims 9 and 17 have been amended to replace the phrase "the gene coding for TB2" with the phrase "the gene coding for the amino acid sequence of SEQ ID No. 1." One of skill in the art will be able to determine the metes and bounds of this claim as amended.

The Examiner has rejected claims 9, 17-19, and 24 as allegedly being indefinite based on the use of the term "ligand." Applicant clarifies that this term means any ligand that binds to TB2. Whether a ligand binds TB2 can be ascertained using the various assays known to one of skill in the art. Therefore, Applicant believes the term ligand as used in the claims is definite and meets the requirements of 112.

The Examiner has also rejected claim 9 because it allegedly requires a step to connect the measured amounts of detectable fluorescence to the determination of degree of inhibition. While applicants disagree that a step was omitted, claim 9 has been amended to clarify that the measured amounts of detectable fluorescence can be used to determine the degree of inhibition.

The Examiner has rejected claim 9 because the use of the term "fluorescence" is allegedly improper. Solely to expedite prosecution, the term "fluorescence" has been replaced with "fluorescent." This amended claim is definite and satisfies 112 because one of skill in the art would be familiar with fluorescent labels and, accordingly, could ascertain the metes and bounds of this claim.

Claims 24 and 25 have been rejected for lacking antecedent basis for the phrase "the method." Applicant has amended these claims to refer to "the assay of claim 9" (in claim 24) and "the assay of claim 24" (in claim 25). These amendments are believed to overcome the Examiner's rejection for lack of antecedent basis.

For the above reasons, Applicant believes that the rejections under 35 U.S.C. § 112 are all improper or rendered moot. The timely withdrawal of the rejections under 35 U.S.C. § 112 is respectfully requested. In view of the above amendments, Applicant believes the pending application is in condition for allowance.

Dated: September 27, 2007

Respectfully submitted,

By


Matthew E. Kelley

Registration No.: 55,887

VENABLE LLP

P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant